PATENT
Attorney Docket No.: 08830-0307US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent application of Richard Frank Tester *et al.*	Conf. No.: 2680
Serial No.:	10/517,558	Art Unit: 1615
Filed:	July 13, 2005	
For:	A Chemical Carrier Based on a Beta-Limit Dextrin	Examiner: Jeffrey T. Palenik

PETITION FROM REQUIREMENT OF RESTRICTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The applicants hereby petition the Director under 37 C.F.R. §§ 1.144 and 1.181 to review the requirement for restriction made in the above-captioned application as between the claims of Group I, constituting claims 1, 3-12, 16, 25 and 36, and the claims of Group III, consisting of claims 26-29 and 37. The requirement of restriction was based upon a lack of unity finding. The Group I claims were elected with traverse. The requirement for restriction was made final in the office action mailed August 19, 2008.

Applicants further petition the withdrawal of claims 36 and 37 from consideration as not being consonant with an election of species made by applicant.

No fee is believed due for the present petition, but if any fee is due the Commissioner is authorized to charge deposit account 50-0573.

CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BY Susan J. Sabzlar

DATE: 1/21/09

Introduction

Independent Claims Subject to Review

Claim 1 is the sole independent claim of Group I. Claim 26 is the sole independent claim of Group III. Those claims are reproduced as follows:

1. A bioadhesive pharmaceutical formulation comprising an active agent and a mucoadhesive carrier for the active agent, wherein the mucoadhesive carrier comprises a ß-limit dextrin.

26. A method for delivering an active agent to a mucosal membrane of a mammal comprising administering to said mammal a bioadhesive formulation comprising said active agent and a mucoadhesive carrier for the active agent, wherein the mucoadhesive carrier comprises a ß-limit dextrin.

Procedural History

The finding of disunity as between Groups I and III was made in the office action mailed October 25, 2007. Group I, at the time of the October 25, 2007 action, consisted of claims 1-12, 16, 23 and 25, directed to a bioadhesive pharmaceutical formulation comprising β-limit dextrin. Group III consisted of claims 26-29, directed to a method for delivering an active agent to a mucosal membrane of a mammal comprising administering a bioadhesive formulation comprising the active agent and mucoadhesive carrier comprising a β-limit dextrin.

In a Response to Restriction Requirement and Amendment filed February 28, 2008, Applicants traversed the lack of unity finding as between Groups I and III, and provisionally elected the claims of Group I. Applicants presented arguments in favor of unity. In response to an election of species requirement for Group I, applicants elected the species of buccal-melt product. The species election requirement was traversed.

In the February 28, 2008 Response, Applicants also added new claims 36 and 37, depending form claims 1 and 26, respectively. Applicants indicated that claims 36 and 37 should be grouped in Groups I and III, respectively. Claims 36 and 37 are reproduced as follows:

36. A bioadhesive pharmaceutical formulation according to claim 1, wherein said formulation is a lyophilized formulation.

37. A method according to claim 26, wherein said formulation is a lyophilized formulation.

In an August 19, 2008 office action, Examiner found the arguments of unity unpersuasive, and maintained the requirement of restriction as between Groups I and III. The Group III claims were withdrawn from consideration. The election requirement was made final. The Group I claims were examined on the merits.

Examiner also withdrew claims 36 and 37 in the August 19, 2008 office action, apparently on the ground that they are not consonant with the elected species of buccal-melt.

Applicants have filed a reply to the August 19, 2008 office action on even date with the filing of the herein Petition. Claims 2 and 23 were cancelled.

Notwithstanding their withdrawal on election of species grounds, claims 36 and 37 are clearly properly grouped in Groups 1 and III respectively. Thus, the claims that have been improperly subject to restriction are as follows, taking into account claims 36 and 37 added in the Response filed February 28, 2008, and taking into account the cancellation of claims 2 and 23 in the reply to the August 19, 2008 office action filed on even date herewith:

Group I: Claims 1, 3-12, 16, 25 and 36; and

Group III: Claims 26-29 and 37.

The Action Requested

The Director is respectfully requested to require that the restriction requirement be withdrawn as between the claims of Group I and III as set forth above, and that the claims of Group III be examined on the merits in the present application.

The Director is further requested to order the removal of claims 36 and 37 from withdrawn status, and their rejoinder with the claims under examination.

Argument

The Groups I and III are Improperly Restricted; Group III Should be Rejoined with Group I

An applicant may petition from a final requirement for restriction if reconsideration of the requirement was requested. 37 C.F.R. § 1.144. Since applicants' requested reconsideration of the restriction requirement in their response filed February 28, 2008, specifically pointing out the errors in the restriction requirement, and since the restriction requirement was made final in the office action mailed August 19, 2008, the applicants are entitled to petition from the requirement of restriction.

Examiner maintains that Groups I and III do not related to a single general inventive concept under PCT Article 13.1 because they lack the same or corresponding special technical feature. Specifically, Examiner alleged in the October 25, 2007 action that "there is no special technical feature since U. S. Patent 4,780,149 teaches the application of β-limit dextrin containing starch hydrosylates via food and pharmaceutical products (column 1, lines 6-9)".

Applicants respectfully submit that Examiner has erred in finding that Patent 4,780,149 deprives the claims of Groups I and III of a special technical feature under PCT Article 13.1. The claims are indeed linked by a special technical feature. The novel formulation as claimed in claim 1 is used in the method of claim 26. The formulation contains an active agent and a muco-adhesive carrier for the active agent, the muco-adhesive carrier comprising a β-limit dextrin.

Although Pat. 4,780,149 makes a passing reference to the use of β-limit dextrin in pharmaceutical products (see column 3 line 26-29), it provides no suggestion whatsoever of the use of β-limit dextrin as a muco-adhesive carrier in a bioadhesive formulation. Indeed, this was acknowledged in the International Preliminary Examination Report (IPER) in relation to the PCT application of which the present application is the US national stage. See the International Preliminary Examination Report, Separate Sheet, "Re Item V", attached. The advantages of using β-limit dextrins as a muco-adhesive carrier for delivery of active agents is not suggested in any way by the prior art.

In responding to applicants' traversal of the lack of unity finding, Examiner has apparently misconstrued applicants' argument as a traversal of the restriction requirement as it

related to Groups I and II, not as between Groups I and III. Although the Examiner does make references to applicants' traversal on the grounds that Groups I and III are linked by a special technical feature, in turning aside that traversal, Examiner relies solely relies on Pat. 4,780,149 and its alleged teaching of the composition of Group II, *i.e.*, relating to the nutritional product of claims 17-19:

> "The Examiner...maintains that the Examples practiced by Kaper et al. (USPN 4,780,149) expressly teach the composition of **Group II** (claims 17-19) wherein a nutritional product comprises β -limit dextrin" (August 19, 2008 office action, p.2, emphasis added)

Examiner's remarks are moot to the extent they are directed to the claims of Group II, since the issue of unity presented is between Groups I and III, not Groups I and II. Moreover, the claims of Groups I and III do in fact share the special technical feature of a bioadhesive pharmaceutical formulation comprising a mucoadhesive carrier comprising beta-limit dextrin. Pat. 4,780,149 does not teach, in any way whatsoever, a bioadhesive pharmaceutical formulation, let alone one in which beta-limit dextrin is a mucoadhesive carrier.

Moreover, in the first complete paragraph of page 3 of the August 19, 2008 office action, the Examiner alleges that the IPER in the international stage explicitly states that the invention set forth in instant claim 1 is neither novel nor inventive. This is a complete misrepresentation of the IPER. In the IPER, in the summary in section V, novelty and inventive step are acknowledged for claims 4-21. In the reasoned statement in section "Re Item V", the Examiner explicitly states that "not disclosed are pharmaceutical formulations of the bioadhesive type". The feature that the pharmaceutical formulation is a *bioadhesive* pharmaceutical formulation appears in claim 4 of the claims under consideration in the IPER (the international application claims as originally filed). The pending claims in the present application had been amended from the PCT claims as referred to in the IPER such that the feature of PCT claim 4 as filed is now included within claim 1 of the instant claims. Accordingly, in complete contrast to the Examiner's allegation, the IPER explicitly indicates that the invention set forth in instant claim 1 is both novel and inventive.

Claim 26, the sole independent claim of Group III, recites a method for delivering an active agent to a mucosal membrane. While claim 26 is not dependent on claim 1, it recites the elements of the bioadhesive formulation of claim 1. Thus, claim 26, and the remaining claims of Group III, share the same special technical feature of claim 1 that distinguishes over the prior art. Accordingly, Group III is properly grouped with Group I.

Applicants request rejoinder of the claims of Group III with the elected claims of Group I now under examination.

Claims 36 and 37 are Improperly Withdrawn and Should be Rejoined with the Claims Subject to Examination

Examiner has withdrawn claims 36 and 37, apparently on the ground that they are not consonant with the elected species of buccal-melt. Examiner alleges that the specification discloses a freeze-dried matrix formulation "as an alternative form independent from both the wafer and powder forms (pg. 14, lines 21-27)". Examiner alleges that given this distinction, had claims 36 and 37 been presented originally, they would have been subject to election of species.

Applicants respectfully submit that Examiner has committed error in withdrawing claims 36 and 37. Applicants submit that Examiner has misinterpreted the disclosure of the application. The specification clearly teaches, and would be understood to teach by the skilled person, that a lyophilized formulation is not mutually exclusive from or independent of the elected species "buccal melt". A *lyophilized* formulation is a state of the formulation, and not a distinct product form constituting a further electable species.

This is apparent from the specification. Page 14, lines 19-21, teaches that the formulation may be a buccal-melt product in one embodiment. Lines 21-27 teach that the formulation may be in a variety of forms, including in particular, capsule, tablet, freeze-dried matrix (i.e. lyophilised) wafer and liquid. Lines 24-27 further teach that the term "particulate product" as used in the specification includes powders, and lines 27-30 teach that "particular products are typically derived from pulverised freeze-dried matrices". Thus, the paragraph to which the Examiner refers does in fact teach that buccal-melt products, as well as other product forms such as powders, *may be freeze-dried*, i.e., lyophilized. Moreover, lines 16-17 describes the use of beta-limit dextrin in freeze-dried matrices and tablets (including melt) type formulations.

Accordingly, new claims 36 and 37, which recite lyophilized formulations, should be treated as readable on the elected species of buccal melt product.

Applicants therefore request rejoinder and examination of claims 36 and 37 with the claims presently being examined.

Respectfully submitted,

RICHARD FRANK TESTER *et al*

BY: _____

DANIEL A. MONACO
Registration No. 30,480
Drinker Biddle & Reath LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
Tel: (215) 988-3303
Fax: (215) 988-2757
Attorney for Applicants